UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 8, 2022

ANIXA BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37492**	**11-2622630**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3150 Almaden Expressway, Suite 250 **San Jose, CA** (Address of principal executive offices)	**95118** (Zip Code)

Registrant's telephone number, including area code: **(408) 708-9808**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	ANIX	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On December 8, 2022, Anixa Biosciences, Inc. ("we," "us," "our," or the "Company") issued a press release announcing that the maximum tolerated dose has been reached in the Phase 1a clinical trial of the Company's preventative breast cancer vaccine technology that is being developed in collaboration with The Cleveland Clinic Foundation (the "Cleveland Clinic"). The press release, which is furnished as Exhibit 99.1 hereto, was issued following a presentation made by certain members of Cleveland Clinic at the San Antonio Breast Cancer Symposium. Furnished hereto as Exhibit 99.2 is the poster utilized for such presentation. Please see our risk factors included in our Annual Report on Form 10-K as well as our other reports filed with the Securities and Exchange Commission for a discussion of the risks associated with our clinical trial.

Statements that are not historical fact may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical facts, but rather reflect our current expectations concerning future events and results. We generally use the words "believes," "expects," "intends," "plans," "anticipates," "likely," "will" and similar expressions to identify forward-looking statements. Such forward-looking statements, including those concerning our clinical trials, involve risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and factors include, but are not limited to, those factors set forth in "Item 1A - Risk Factors" and other sections of our most recent Annual Report on Form 10-K as well as in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this Current Report.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibits are filed with this Current Report on Form 8-K:

Exhibit No.	Description
99.1	Press Release
99.2	Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: December 8, 2022

ANIXA BIOSCIENCES, INC.

By: */s/ Michael J. Catelani*
Name: Michael J. Catelani
Title: President, Chief Operating Officer and Chief Financial Officer

Anixa Biosciences Announces Maximum Tolerated Dose Reached in Trial of Preventative Breast Cancer Vaccine

SAN JOSE, Calif., Dec. 8, 2022 /PRNewswire/ -- Anixa Biosciences, Inc. (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer and infectious diseases, today announced the maximum tolerated dose (MTD) has been reached in the Phase 1a trial of its preventative breast cancer vaccine.

The trial is an open-label, multiple-ascending dose Phase 1a trial to evaluate safety and monitor immune response after vaccination. A critical goal was to determine the maximum tolerated dose of the vaccine. The MTD is the highest dose of a medicine or treatment that will produce the desired effect without resulting in unacceptable side effects. Higher concentrations may be effective but may induce side effects that deter use or outweigh the benefits of treatment. The MTD will guide dosing in successive Phase 2 and Phase 3 trials. Recently, a Phase 1b trial was commenced, based on the results to date of the Phase 1a trial. The Phase 1a and Phase 1b trials are currently being conducted at Cleveland Clinic and include women who have previously been diagnosed with triple negative breast cancer and are currently cancer free and at risk of recurrence, and healthy cancer free women at high risk for developing breast cancer in the future, respectively. Future trials are expected to be conducted at multiple sites.

"We are pleased to have reached this important milestone in the clinical development of our preventative breast cancer vaccine, and we look forward to completing enrollment for the Phase 1a trial," stated Dr. Amit Kumar, Chairman and CEO of Anixa. "After the last participant is vaccinated and completes all follow up tests, we will compile and analyze the data. We look forward to presenting the complete immunological data from the trial at a scientific conference or similar setting in the second quarter of 2023."

About Anixa Bioscience's Breast Cancer Vaccine
Anixa's breast cancer vaccine, currently in Phase 1 trials, takes advantage of endogenously produced proteins that have a function at certain times in life, but then become "retired" and disappear from the body. One such protein is a breast-specific lactation protein, α-lactalbumin, which is no longer found post-lactation in normal, aging tissues, but is present in the majority of triple-negative breast cancers. Activating the immune system against this "retired" protein provides preemptive immune protection against emerging breast tumors that express α-lactalbumin. The vaccine also contains an adjuvant that activates an innate immune response, which allows the immune system to mount a response against emerging tumors to prevent them from growing. This vaccine technology was invented by Dr. Vincent Tuohy, Mort and Iris November Distinguished Chair in Innovative Breast Cancer Research in the Department of Inflammation and Immunity at Cleveland Clinic's Lerner Research Institute. Dr. Tuohy is named as inventor on the technology, which Cleveland Clinic exclusively licensed to Anixa Biosciences. Dr. Tuohy will receive a portion of commercialization revenues received by Cleveland Clinic for this technology and also holds personal equity in Anixa.

About Anixa Biosciences, Inc.
Anixa is a clinical-stage biotechnology company with programs addressing cancer and infectious disease. Anixa's portfolio of therapeutics includes a cancer immunotherapy program being developed in collaboration with Moffitt Cancer Center, which uses a novel type of CAR-T, known as chimeric endocrine receptor T-cell (CER-T) technology, and, with partner MolGenie GmbH, a COVID-19 program focused on compounds targeting the M^{pro} enzyme of SARS-CoV-2, which is largely conserved across all recently identified variants. The company's vaccine portfolio includes a novel vaccine being developed in collaboration with Cleveland Clinic to prevent breast cancer – specifically triple negative breast cancer (TNBC), the most lethal form of the disease – as well as a vaccine to prevent ovarian cancer. These vaccine technologies focus on immunizing against "retired" proteins that have been found to be expressed in certain forms of cancer. Anixa's unique business model of partnering with world-renowned research institutions on clinical development allows the company to continually examine emerging technologies in complementary fields for further development and commercialization. To learn more, visit www.anixa.com or follow Anixa on Twitter, LinkedIn, Facebook and YouTube.

Forward-Looking Statements: Statements that are not historical fact may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical facts, but rather reflect Anixa's current expectations concerning future events and results. We generally use the words "believes," "expects," "intends," "plans," "anticipates," "likely," "will" and similar expressions to identify forward-looking statements. Such forward-looking statements, including those concerning our expectations, involve risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and factors include, but are not limited to, those factors set forth in "Item 1A - Risk Factors" and other sections of our most recent Annual Report on Form 10-K as well as in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this press release.

Contact:
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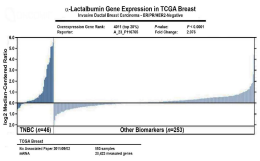
mcatelani@anixa.com
408-708-9808

Phase I trial of an alpha-lactalbumin vaccine in patients with operable triple-negative breast cancer (TNBC)

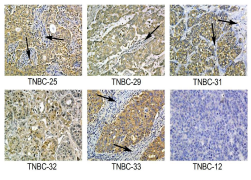
G. Thomas Budd, Justin M. Johnson, Emily E. Rhoades, Halle C. F. Moore, Megan L. Kruse, Erin E. Roesch, Jame Abraham, Brenna Elliot, Elena Haury, Vincent K. Tuohy
Cleveland Clinic, Cleveland, OH

San Antonio Breast Cancer Symposium®
December 6-10, 2022
OT2-10-02
Abstract ID:1304814

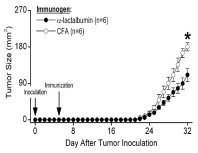
BACKGROUND



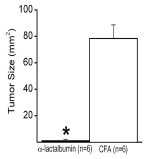
- α-lactalbumin normally expressed only in lactating breast tissue
- Oncomine database search of TCGA shows overexpression of α-lactalbumin gene in TNBC *vs.* other breast cancers



Immunohistochemical detection of α-lactalbumin protein in parenchyma of human TNBC tumors. 5/6 (83%) showed reactivity ranging from weak (TNBC-32) to moderate (TNBC-33). Arrows show no immunostaining in tumor stroma.
Cancers PMID: 27322324



Inhibition of growth of 4T1 tumor growth with α-lactalbumin immunization 5 days after tumor inoculation (*$P < 0.01$).
Nat Med PMID: 20512124



Growth of autochthonous breast tumors in 10-month-old MMTV-*neu* mice immunized with α-lactalbumin at 8 weeks of age (*$P = 0.0004$).
Nat Med PMID: 20512124

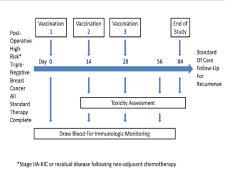
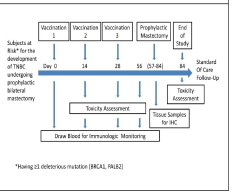
STUDY DESIGN

- "3+3" Phase I trial design
- Vaccine contains α-lactalbumin antigen and zymosan adjuvant in Montanide ISA VG 51 vehicle
- Three vaccinations given at two-week intervals at Day 0, Day 14, and Day 28
- Toxicity monitored until Day 84 or resolution of toxicity
- CTCAE Grade ≥2 is dose limiting
- Immunologic monitoring from blood draw just prior to each immunization and at Day 56
  - ❖ ELISpot assays for IFNγ and IL-17
  - ❖ ELISA assays for α-lactalbumin antibody

DOSING SCHEME

Dose Level	Dose α-lactalbumin	Dose Zymosan	Subjects Enrolled
1	10 μg	10 μg	3/3
2	100 μg	10 μg	3/3†
3	500 μg	10 μg	3/3*
4	500 μg	30 μg	
5	500 μg	60 μg	

†MTD established; cohort to be expanded to n=6
*Limiting toxicity observed in 1/3 subjects

Phase Ia TNBC Cohort	Phase Ib Prevention Cohort
	

ELIGIBILITY CRITERIA

Phase Ia TNBC Cohort	Phase Ib Prevention Cohort
• Stage II-III TNBC • Completed all standard therapy • Within 3 years of diagnosis • No evidence of recurrence	• High-risk genetic mutation (*BRCA1, PALB2*) carriers planning to undergo prophylactic bilateral mastectomy • No evidence of breast cancer

OBJECTIVES

For both Phase Ia TNBC and Phase Ib Prevention Cohorts

- Primary: Determine Maximum Tolerated Dose
- Secondary: Determine Lowest Immunologic Dose
- Exploratory: Establish Optimal Immunologic Dose
- Correlative: Examine the immune response to α-lactalbumin using ELISpot and ELISA

CURRENT STATUS

Phase Ia TNBC Cohort	Phase Ib Prevention Cohort
• Currently enrolling • Limiting toxicity reached at Dose Level 3 • MTD established at Dose Level 2 • Dose Level 2 to be expanded to n=6 • Intermediate doses may be explored	• Open to accrual • Subjects in the prevention cohort will be enrolled in dose levels at or below the maximum tolerated dose based on the TNBC cohort

FUTURE DIRECTIONS

- Expansion of Phase Ia MTD Dose Level 2 cohort
- Exploration of intermediate doses
- Add cohort to test vaccine adjuvant therapy with checkpoint inhibitor pembrolizumab

ACKNOWLEDGMENTS

Supported by Department of Defense
Award Numbers:W81XWH-17-1-0592; W81XWH-17-1-0593

Contact: buddg@ccf.org

Cleveland Clinic